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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/545,998	04/10/2000	Daniel M. Gorman	DX0612K1B	7858

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EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	PAPER NUMBER
1644	14

DATE MAILED: 01/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

# Office Action Summary	Application No. 09/545,998	Applicant(s) Gorman et al.
	Examiner Ron Schwadron, Ph.D.	Art Unit 1644

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on ______.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *6 and 23-30* is/are pending in the application.

4a) Of the above, claim(s) ______ is/are withdrawn from consideration.

5) ☐ Claim(s) ______ is/are allowed.

6) ☒ Claim(s) *6 and 23-30* is/are rejected.

7) ☐ Claim(s) ______ is/are objected to.

8) ☐ Claims ______ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on ______ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on ______ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ______.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). ______
4) ☐ Interview Summary (PTO-413) Paper No(s). ______
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. Claims 6,23-30 are under consideration.

RESPONSE TO APPLICANTS ARGUMENTS

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 30 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the kit of claim 30. Regarding applicants comments, claim 6 is drawn to antibody, whilst original claim 12 was drawn to a Markush group (albeit improper). Neither of these claims discloses the claimed kit. The specification, page 47, lines 8-16 discloses kits with the labeled antibody, the protein/peptide recited in the claims, and a "solid phase" for immobilizing the protein, wherein said kit also includes compartments and instructions. However, the claimed kit recites the protein/peptide immobilized to a solid support wherein the "solid support" and the preimmobilized peptide are not disclosed in the specification as originally filed (eg. the solid phase is a separate component). Said passage of the specification also discloses that the kit containing instructions also has compartments, wherein said compartments are not recited in the claimed kit. There is no disclosure of the scope of the claimed invention in the specification as originally filed (eg. the claimed invention constitutes new matter).

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claim 6,26 stand rejected under 35 U.S.C. 102(e) as being anticipated by Baum et al. (US Patent 5,457,035). Applicants arguments have been considered and deemed not persuasive.

Baum et al. teach monoclonal antibodies which bind OX40-L (see column 24). Said antibodies would bind any epitope on OX40-L. OX40-L has amino acid sequences in common with SEQ. ID. NO. 4 (for example amino acids 139-143 of OX40-L (columns 31-32) are found in SEQ. ID. NO. 4). The specification does not disclose what amino acid subsequences of SEQ. ID. NO. 4 actually constitute antibody epitopes. However, antibodies which bind amino acids 139-143 of OX40-L would bind the same sequence in SEQ. ID. NO. 4.

Regarding applicants comments, the specification, page 16, lines 28-37 actually does not define what "specifically binds a protein" means or encompasses. Lines 28-37 of the specification refer to antibodies that are "specifically immunoreactive with that particular protein *and not with other proteins*". Thus, the aforementioned two properties are not necessarily connected, and said phrase refers to "specifically immunoreactive", not "specifically binds". The specification, page 16, lines 28-30 disclose that "Specific binding to an antibody under such conditions may require an antibody that is selected for its specificity for a particular protein". Thus, the aforementioned two properties are not necessarily connected. Furthermore, the specification, page 16 lines 16-29 **actually defines "specifically binds to an antibody" as meaning that the antibody binds an epitope and that the epitope is found in a protein.** Said definition does not state that the epitope is only found in a protein/peptide of SEQ. ID. NO:2 or 4. Thus, the properties of "specific binding" and not reacting with other proteins are not necessarily connected. Applicants arguments involve limitations not currently recited in the claims under consideration.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 6,23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baum et al (US Patent 5,457,035) in view of Godowski et al. (US Patent 5709858). Applicants arguments have been considered and deemed not persuasive.

Baum et al. teach monoclonal antibodies which bind OX40-L (see column 24). Said antibodies would bind any epitope on OX40-L. OX40-L has amino acid sequences in common with SEQ. ID. NO. 4 (for example amino acids 139-143 of OX40-L (columns 31-32) are found in SEQ. ID. NO. 4). The specification does not disclose what amino acid subsequences of SEQ. ID. NO. 4 actually constitute antibody epitopes. However, antibodies which bind amino acids 139-143 of OX40-L would bind the same sequence in SEQ. ID. NO. 4. Baum et al. do not teach the claimed antibody composition, antibody fragments or antibodies of claims 24,25, 29. Godowski et al. teach antibody fragments, humanized antibodies, labeled antibodies and immobilized antibodies wherein said molecules are produced using art known methods and wherein said reagents have well known uses (see columns 36-39). Said molecules would have been produced based on any known antibody. The antibodies would have been prepared in a composition containing buffer for use in a variety of art known methods (immunoassays, affinity purification, etc). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Baum et al. teach monoclonal antibodies which bind SEQ. ID. NO. 4 and Godowski et al. teach antibody fragments, humanized antibodies, labeled antibodies and immobilized antibodies wherein said molecules are produced using art known methods and wherein said reagents have well known uses.

Applicants arguments are the same as addressed in paragraph 5 of this Office Action.

8. No claim is allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this

Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644